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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,090

10/17/2003

Rubinah K. Chowdhary

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05/17/2006

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/688,090	<b>Applicant(s)</b> CHOWDHARY ET AL.	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,7-14,18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-14,18 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/24/03 &amp; 1/21/05</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, remarks and amendment filed 2/28/06. Claims 1, 7-14, 18 and 21 are pending.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The rejection claims 7 and 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment.

4. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

5. Claims 1, 7-14, 18 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

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To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. There is no description in the specification for composition excluding all fluorocarbons. There is no description in the as filed specification for compositions excluding or including the specific poloxamer 188 modulators.

Claims employing exclusion or inclusion of poloxamer 188 are neither described nor exemplified and the specification does not inform the public of the limits of the monopoly asserted. Specifically, the specification at paragraph [0017] of the published application excludes Pluronic F-68. Pluronic F-68 is not the same as poloxamer 188 (registry file on STN). Certain poloxamers are specifically listed in paragraphs [0088] and [0090] of the published specification as useful in the instant specification. Poloxamer 188 is neither included nor excluded in the invention according to the description of the invention.

6. Claim 7 recites the limitation "micelle" and "emulsion " in lines 2 and 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 7 is dependent on claim 1, Claim 1 requires the complex to be a solid. Claim 7 requires the complex to be micelle or emulsion and micelle or emulsion is not a solid. Claim 1 does not therefore, provide support for micelle or emulsion.

7. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. F68 is placed in parenthesis and since poloxamer 188 is not Pluronic 68, it is not clear what that parenthetical expression is conveying. The claim is thus confusing and is not rejected under art.

***Claim Rejections - 35 USC § 102***

8. Claims 1, 7, 8, 10-14 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Richter et al. (US 6,274,614).

Richter discloses composition comprising photosensitizing agent and absorbent applicator (abstract) and physiologically acceptable carriers (column 12, lines 13-17). The photosensitizing agent can be administered as liquid, gel or gelatinous solid pharmaceutical composition (column 17, lines 32-34). Richter discloses a broad teaching of Poloxamer as suitable surfactants for use with the porphyrines (column 18, line 65 to column 19 line 6); Richter specifically discloses that lyophilized formulation is suitable for storage (column 19, lines 10-16). Lyophilizing the emulsion would form a solid and would meet the limitations of a solid formulation. Furthermore, Richter discloses that the photosensitizing agent is administered in liquid, gel, or solid pharmaceutical composition (column 17, lines 32-34). Green porphyrines and derivatives are examples of the photosensitizing agent used in Richter (column 11, line 38 to column 17 line 10); the chlorine system is also used (column 14, line 66 to column 15 line 3). A sponge is saturated with the photosensitizer containing liposomal BPD (a hydromonobenzoporphyrin derivative) and the BPD saturated sponge is placed in contact with the tissue to be treated (column 22, lines 17-25). Claim 21 reads on the BPD saturated sponge, the solid support reading on the sponge. Richter does not disclose polystyrene polymer and does not disclose the use of poloxamer 188 when fluorocarbons are not used. However, Richter discloses that FLUOSOL-DA containing perfluorodecalin and perfluorotripropylamine specifically discloses poloxamer 188 or Pluronic F 68 for use with perfluorodecalin. Richter does not include FC43, PP11 and PP25 fluorocarbons in the composition.

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***Response to Arguments***

9. Applicant's arguments filed 2/28/06 have been fully considered but they are not persuasive.

Regarding applicant's argument that Richter discloses a genus and not species, it is noted that claim 1 is generic to photosensitizer and block copolymer while Richter discloses a porphyrine, and specifically green porphyrines, which is a species of photosensitizer. Poloxamer is also a species of the block copolymer recited in claim 1. Richter also specifically discloses that the chlorine (found in instant claim 12) system is a dihydro form of the porphyrine while the reduced chlorin system is a tetrahydro form of the conjugated porphyrine (column 14, line 67 to column 15, line 3). Therefore, Richter discloses the species that anticipates the genus in claim 1, at least. There is also no selective combination of various disclosures within the reference to arrive at the claimed invention. If a matrix is a solid, then Richter meets the limitation. Also, Richter specifically discloses administering the composition in the form of a liquid, gel, or solid pharmaceutical composition (column 17, lines 32-34). The recitation of micelle and emulsion has no support in claim 1 that requires the complex to be a solid. Rejection is therefore maintained.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. The rejection of claims 1, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajagopalan et al. (WO 99/51284, reference provided by applicants in Form PTO 1449) is withdrawn because Rajagopalan does not disclose a solid formulation. Rajagopalan, however discloses poloxamer 188 and photosensitizer, so that Rajagopalan meets the limitation of claim 18, but because the claim is indefinite and an unambiguous interpretation can not be made, the rejection is not made at this time.

Applicant's argument with respect to Rajagopalan is thus moot in view of the withdrawal of the rejection.

12. The rejection of claims 1 and 7-14 under 35 U.S.C. 103(a) as being unpatentable over Lyons (US 5,616,342) is withdrawn because t Lyons does not disclose a solid.

13. The rejection of claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over Lyons (US 5,616,342) is withdrawn partially in view of the cancellation of claim 19 and partly because claim 18 is unclear and confusing.

Thus applicant's argument with respect to Lyons is moot in view of the withdrawal of the rejections.

14. Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Busman et al. (US 4,511,641).

Busman discloses a composition that comprises photosensitizer and surfactant; pluronic F-127, F-68 and F-65 are some of the specific surfactants suggested by the Busman art for formulation with the photosensitizer (abstract, Table VIII, Examples 36-86; column 15, lines 29-31; column 18, lines 28-35 and 53-62). While there is no exemplification of a photosensitizer in combination with F-127, F-68 and F-65, there is a suggestion that the photosensitizer can be

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formulated with surfactants such as F-127, F-68 and F-65. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a combination of surfactant and photosensitizer. One having ordinary skill in art would have been motivated to use one of the suggested surfactant with expectation that the formulation can deliver the photosensitizer.

15. The prior art made of record and not relied upon is considered pertinent to applicants' disclosure.

Stewart et al. (WO 98/34644, provided by applicants in Form PTO 1449) discloses a composition comprising a photosensitizing agent and one or more physiologically acceptable carriers (page 28, lines 21-28). The photosensitizing agent is administered alone or with water or other pharmaceutically acceptable excipients in a liquid, gel or gelatinous composition (page 29, lines 7-24). The photosensitizing composition comprises a poloxamer surfactant block copolymer (page 31, lines 25-27). Stewart's photosensitizing agents are benzoporphyrin compounds selected from BPD-MA, BPD-MB, BPD-DA and BPD-DB (page 27, line 9 and claims 4 and 21). Stewart discloses a method of reducing or preventing the effects of inflammation that results from injury to tissues and the method comprises the steps of contacting the injured tissue with the photosensitizing composition and exposing the treated tissue to light of the appropriate energy to photodynamically treat the injured tissue (abstract, page 1, lines 5-15). Stewart further discloses that the photosensitizing agent may be combined with one or more immunosuppressive agents to enhance the anti-inflammatory effect of the photosensitizing agent (page 30, lines 10-13). The poloxamer block copolymer of Stewart encompasses all form the poloxamer. The emulsion-forming agent is a fluorocarbon.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

A handwritten signature in black ink, appearing to read 'MB Fubara', is written over the printed name 'Blessing Fubara'.